ASX ANNOUNCEMENT

FDA Decision for FebriDx

MELBOURNE, Australia (11 July 2022): Lumos Diagnostics (ASX: LDX) has been advised by the US Food and Drug Administration (FDA) that, following its review of Lumos' 510(k) application, FebriDx® did not demonstrate substantial equivalence to the predicate device and consequently has not been granted clearance for marketing in the U.S. The Company is currently reviewing the feedback provided by the FDA in order to determine the next steps.

This decision was based on the FDA's evaluation of data for FebriDx during the review process. The proposed intended use of FebriDx is as an aid to differentiate bacterial from viral infections and the test met success criteria defined before the pandemic in accordance with the pre-submission. However, given the number of reported cases and deaths from SARS-CoV-2 in the U.S., the FDA expressed concerns regarding the risk that false negative viral infection test results could lead to missed opportunities to treat patients or contribute to the further spread of SARS-CoV-2 infections. Lumos has previously received regulatory registrations for the use of FebriDx in the UK, Europe, Canada, UAE, Brazil and Australia.

In light of these concerns, and Lumos' belief in the potential of this product to assist in addressing the global challenge of antimicrobial resistance, Lumos is evaluating options to secure a potential regulatory clearance by the U.S. FDA for FebriDx. This is expected to include an appeal to the FDA that would result in a decision within 90 days of submission, or a potential new 510(k) submission. Led by CEO Doug Ward, the senior management team is currently conducting a deep dive into relevant correspondence between Lumos and the FDA to ensure Lumos has the most comprehensive and appropriate evidence to address the FDA's feedback as part of an appeal process.

"Clearly this was not the outcome that the Company was seeking and this decision from the FDA is a significant disappointment for Lumos," said Doug Ward, Chief Executive Officer of Lumos. "The U.S. launch of FebriDx was a key component of Lumos' future commercial plans. I will be actively working with our regulatory team and advisors to review this feedback and to develop a revised commercial plan for Lumos to incorporate this unexpected development."

Investor webinar – 11am AEST today

Lumos Diagnostics invites shareholders and other interested parties to a webinar hosted by Executive Chair Sam Lanyon and CEO Doug Ward, discussing today's announcement regarding the FDA decision for FebriDx.

The webinar will be held today, Monday 11 July 2022 at 11am AEST.

For the Q&A session, investors are encouraged to send questions prior to the webinar to matt@nwrcommunications.com.au.

Register for the webinar at the link below:
https://us02web.zoom.us/webinar/register/WN_KacZZ-K1SBeZQ_Aq2R9cqg

After registering, you will receive a confirmation email containing information about joining the webinar as well as dial-in details for those that would prefer to join by phone. A recording will be available at the above link shortly after the conclusion of the live session.

This announcement has been approved by the Lumos Disclosure Committee

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About Lumos Diagnostics

Lumos Diagnostics specialises in rapid, cost-effective, and complete point-of-care (POC) diagnostic test technology to help healthcare professionals more accurately diagnose and manage medical conditions. Lumos offers customised assay development and manufacturing services for POC tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercialises novel Lumos-branded POC tests that target infectious and inflammatory diseases.

For more information visit lumosdiagnostics.com.

Forward-Looking Statements

This announcement contains forward-looking statements, including references to forecasts. Forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions, and other important factors, many of which are beyond Lumos' control and speak only as of the date of this announcement. Readers are cautioned not to place undue reliance on forward-looking statements.

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